

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dioderm 0.1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 0.1% w/w.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Smooth white aqueous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of eczema and dermatitis.

4.2 Posology and method of administration

For adults, the elderly and children
Apply to the affected areas twice daily.

For infants

Although generally regarded as safe, there is a potential for overdosage in infancy. Extreme caution is therefore required in dermatoses in infancy, including napkin eruption. In such patients, courses of treatment should not normally exceed 7 days.

4.3 Contraindications

As with all topical steroids, Dioderm is not to be used where there is bacterial, viral or fungal infection.
Not to be used on open wounds, ulcers or broken skin.
Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Prolonged or extensive uninterrupted application should be avoided, particularly if used on the face or with occlusive dressings.

Keep away from the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Reported side effects of corticosteroids include skin thinning and striae. Although rare, these could occur even with hydrocortisone, especially when used under occlusion or in the folds of the skin.

Dioderm is usually well tolerated although the excipient propylene glycol may on rare occasions cause skin irritation in sensitive people. In the rare event of skin irritation or a hypersensitivity reaction (allergic contact dermatitis) treatment should be discontinued.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Under exceptional circumstances, if Dioderm is used excessively, particularly in young children, it is theoretically possible that adrenal suppression and skin thinning may occur. The symptoms are normally reversible on cessation of treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Corticosteroids are used in pharmacological doses for their anti-inflammatory and immunosuppressive glucocorticoid properties which suppress the clinical manifestations of a wide range of diseases. Although many synthetic derivatives have been developed, hydrocortisone is still used widely in topical formulations for inflammatory dermatoses. It has the advantage over its synthetic derivatives that it is metabolised in the skin and therefore cannot accumulate to cause local side effects.

5.2 Pharmacokinetic properties

The cream formulation of Dioderm was developed in order to optimise the release and partition of its active ingredient, hydrocortisone, into the skin. The hydrocortisone is presented as a saturated or near saturated solution in aqueous propylene glycol, which represents the continuous phase of the emulsion system. It has been shown, by the vasoconstrictor assay on normal skin, that in this environment, a 0.1% concentration of the hydrocortisone is equivalent to the 1.0% concentration of the official cream formulations appearing in the British Pharmacopoeia where the drug substance is in suspension. Clinical studies have confirmed that 0.1% Dioderm is equivalent to 1.0% Hydrocortisone Cream BP whilst the reduced strength of Dioderm increases the margin of safety.

5.3 Preclinical safety data

The presentation of preclinical safety data is considered inappropriate due to the fact that the safety and efficacy of hydrocortisone in topical dosage forms has been well established over many years of widespread clinical usage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid
Emulsifying wax
White soft paraffin
Liquid paraffin
Propylene glycol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C. Replace cap tightly after use.

6.5 Nature and contents of container

Membrane sealed aluminium collapsible tube with a high density polyethylene white spiked flowerpot screw cap inverted over the orifice to break the seal.

The tube contains 30g of cream.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dermal Laboratories Ltd
Tatmore Place
Gosmore
Hitchin
Herts SG4 7QR
UK

8 MARKETING AUTHORISATION NUMBER

PA 278/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 December 1980

Date of last renewal: 01 December 2005

10 DATE OF REVISION OF THE TEXT

February 2015